K053430

MAR 3 2006

510(k) Summary

510(k) Owner	Medtronic Xomed, Inc 6743 Southpoint Drive North Jacksonville, FL 32216-0980 USA 904-296-9600 904-296-2386 (FAX)
Contact Name	Penny M. Layman Regulatory Manager, Sustaining Business Medtronic Xomed, Inc.
Date Summary Prepared	November 30, 2005
Proprietary Name	Tono-Pen AVIA™ tonometer with Ocu-Shield™ tip cover
Common Name	Tonometer, Manual
Classification Name	Tonometer and accessories (21 CFR 886.1930, Product Code HKY)

Marketed device claiming equivalence to

The Tono-Pen AVIA with Ocu-Shield is equivalent to the Mentor Tono-Pen 3, K964312. The accessory tip cover is similar to the Oculab Ocu-Film tip cover, K882750. The current Medtronic Xomed tonometer is named the Tono-Pen XL.

Device Description

The Tono-Pen AVIA is a precision electronic manual tonometer which measures intraocular pressure. The body of the instrument is ergonomically designed to fit comfortably in the user's hand to facilitate a technique that helps to ensure fast, precise measurements. The sensor must be covered with an Ocu-Shield tip cover to help protect the patient from cross contamination as well as provide protection of the sensor.

Intended Use

The Tono-Pen AVIA tonometer is used to measure the IntraOcular Pressure (IOP) during routine eye examination or when an increased IOP is suspected.

The Ocu-Shield tip cover is used to help protect the patient from cross contamination and protect the Tono-Pen AVIA sensor from eye fluids during use or debris during storage.

Indications for Use

The indications for use include measuring intraocular pressure for suspected glaucoma or when an increased intraocular pressure is suspected.

Performance Characteristics

The Tono-Pen AVIA is an ergonomic hand held tonometer that measures intraocular pressure. The tip of the tonometer contains a sensor that houses a transducer assembly

that converts applied pressure into an electrical signal. The electronics housed in the ergonomic Tono-Pen AVIA body, process and analyze the waveforms produced by each touch of the corneal surface of the eye, to produce an averaged IOP measurement. The measurement along with the number of data points collected is displayed on the Liquid Crystal Displays (LCD). The Ocu-Shield is a protective membrane shaped to cover the tip and is used to protect the patient from cross contamination, and when used during storage, protects the sensor from damage. A replaceable battery compartment houses the Tono-Pen AVIA POWERCEL lithium manganese dioxide batteries.

Summary of Tonometer Technological Characteristics

	Mentor Tono-Pen 3 K964312	**Medtronic Xomed Tono-Pen AVIA** —
Indications for Use	The Mentor TONO-Pen 3 is used to measure the intraocular pressure (IOP) during routine eye examination or when an increased IOP is suspected.	The Medtronic Xomed Tono-Pen AVIA is used to measure the intraocular pressure (IOP) during routine eye examination or when an increased IOP is suspected.
Transducer type	Elemental silicon, diaphragm type strain- gage transducer	Elemental silicon, diaphragm type strain-gage transducer
Microprocessor	8 Bit Processor	10 Bit Processor
Software	Assembly	C++
Body material	Molded ABS plastics	Molded ABS plastics
Display	One Liquid Crystal Display (LCD) Display on one side	Two Liquid Crystal Displays (LCD). Display on both sides for left or right handed user.
Power Source	Two 3.0 volt lithium manganese dioxide batteries	Two 3.0 volt lithium manganese dioxide batteries
Operating Life	Five years of average use (2500 uses/year)	Five years of average use (2500 uses/year)
User interface	The Tono Pen 3 is held as you would a pencil, with the index finger on the activation switch. Once activated, the user touches the cornea lightly and briefly and withdraws the device. A reading will be displayed on the LCD. After four readings an average IOP will appear as well as the reliability of the average number shown.	The Tono-Pen AVIA is a curved, ergonomically shaped device with the index finger used for the activation switch. Once activated, the user touches the cornea lightly and briefly. A reading will be displayed on both LCDs for ease of use by either a right or left handed person. After 10 readings an average IOP will appear as well as the number of data points collected.
Range of measurement	5-80 mmHg	5-55 mmHg
Calibration / Verification	Recommended once daily	Recommended once daily.

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Summary of Tip Cover Technological Characteristics

	Oculab, Inc. Ocu-film K882750	**Medtronic Xomed Ocu-Shield —**
Intended Use	Protective membrane to prevent transmission of infection between patients as well as provide protection to the transducer tip.	The Ocu-Shield tip cover is used to help protect the patient from cross contamination and protect the Tono-Pen AVIA sensor from eye fluids during use or debris during storage.
Material	Natural Rubber Latex	Polyethylene
Shape	Finger Cover design	Molded to AVIA transducer shape
Tip Thickness	.003"	.0008"
Packaging Configuration	Individually placed on a tubular cardboard insert and packed in a box of 90	Multi-Pack dispensers, box of 180 Single Pack, Individual plastic cups, sealed with a Tyvek cover
Provided	Non-sterile, sanitized	Multi pack: Non-sterile, sanitized Single pack: Sterile
Sterilization / Sanitization Method	Gamma Irradiation	Gamma Irradiation
Shelf Life	3 Years	3 Years

Summary of Non-Clinical Testing

Biocompatability

The Ocu-Shield tip cover is considered biocompatible for use as a surface device with mucosal membrane contact of less than 24 hours. The appropriate tests were performed according to;

- ISO 10993-1:2003, Biological evaluation of medical devices – Part 1 Evaluation and Testing
- FDA G95-1, Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May 1, 1995

Shelf Life Aging, Tip Cover

The tip covers met the acceptance criteria in the initial shelf life functional testing for tonometer accuracy.

Operating Life, Tonometer

The battery pack met the acceptance criteria for providing the tonometer with a 2500 nominal operating life.

Bench testing

The units under test met the acceptance criteria of the operating range, accuracy, repeatability, sensitivity, angle of incidence and battery life.

Electromagnetic Compatibility and Electrical Safety Testing

The RF emission and immunity testing, magnetic immunity and ESD testing passed for the Tonometer testing performed to BS EN 60601-1 and BS EN 60601-1-2 requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 2006

Medtronic Xomed, Inc.
% Penny Layman
6743 Southpoint Dr. N
Jacksonville, FL 32216

Re: K053430
Trade/Device Name: Tono-Pen AVIA
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and accessories
Regulatory Class: Class II
Product Code: HKY
Dated: February 1, 2006
Received: February 2, 2006

Dear Ms. Layman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Acting Division Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Unknown~~ K053430

Device Name: Tono-Pen AVIA™ tonometer and Ocu-Shield™ tip cover

Indications for Use:

The indications for use include measuring intraocular pressure for suspected glaucoma or when an increased intraocular pressure is suspected.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) Or Over-the-Counter Use (Per 21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Clay R. Butler

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

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